

**REMARKS**

Of claims 1-55 which were contained in the pending application, all claims remain. The informalities contained claims 1-9, 13, 15, 21, 25, 31, 34, 51 and 52 have been corrected (§2 of the 02252008 office action).

**Rejections Under 35 U.S.C. §112, second paragraph**

The Examiner has rejected claims 8-10, 15, 18-20, 22, 24, 34-36 and 46 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

The Examiner maintains that there is no antecedent basis in claim 1 for “functional number of initiator” (claim 8). Claim 8 has been amended to correct for this lack of antecedent basis and no new matter is introduced as a result of this amendment.

The Examiner maintains that there is no antecedent basis in claim 7 for “the lactone monomers (claim 9, line 2). Claim 9 has been amended to correct for this lack of antecedent basis and no new matter is introduced as a result of this amendment.

The Examiner maintains that there is no antecedent basis in claim 7 for “the carbonate monomer” (claim 10, line 2). Claim 10 has been amended to correct for this lack of antecedent basis and no new matter is introduced as a result of this amendment.

The Examiner maintains that there is no antecedent basis in claim 14 for “said flavoring agent” (as it appears in claims 18 and 20). Claim 14 contains the language “... wherein said chewing gum ingredients comprise flavoring agents.” Claims 18 and

20 refer to “flavoring agents.” Accordingly, there is sufficient antecedent basis found in claim 14 for “flavoring agents”.

The Examiner maintains that there is no antecedent basis in claim 18 for “said water-soluble flavoring agent” (as it appears in claim 19). Claim 19 has been amended to correct for this lack of antecedent basis and no new matter is introduced as a result of this amendment.

The Examiner maintains that there is no antecedent basis in claim 21 for “said sweetener” (as it appears in claims 22 and 24). Claim 21 contains the language “...wherein said chewing gum ingredients comprise *sweeteners*.” Claims 22 and 24 recite “said sweeteners”, referring back to claim 21. Accordingly, there is sufficient antecedent basis found in claim 21 for “sweetener”.

The Examiner maintains that there is no antecedent basis in claim 33 for “the lactone monomers” (claim 34, line 2). Claim 34 has been amended to correct for this lack of antecedent basis and no new matter is introduced as a result of this amendment.

The Examiner maintains that there is no antecedent basis in claim 33 for “the carbonate monomers” (claim 35, line 2). Claim 35 has been amended to correct for this lack of antecedent basis and no new matter is introduced as a result of this amendment.

The Examiner maintains that there is no antecedent basis in claim 6 for “polyester ... monomers” (claim 36, lines 2-3). Claim 36 has been amended to correct for this lack of antecedent basis and no new matter is introduced as a result of this amendment.

The Examiner maintains that claim 9 is indefinite since it is not clear what is intended by “and mixtures thereof.” Claim 9 has been amended and no new matter is introduced as a result of this amendment.

The Examiner maintains that claim 15 is indefinite in reciting “other ... profile” (last line). Claim 15 has been amended and no new matter is introduced as a result of this amendment.

The Examiner maintains that claim 46 is indefinite in reciting “and an agent ... polymer” (last 2 lines). Claim 46 has been amended and no new matter is introduced as a result of this amendment.

Accordingly, the rejections under 35 U.S.C. §112, second paragraph, have been overcome and should be withdrawn.

#### **Rejections Under 35 U.S.C. §103(a)**

(¶6) The Examiner has rejected claims 1-39 and 49-55 under 35 U.S.C. §103(a) as being unpatentable over Grijpma et al. (USP 5,672,367). In making this rejection, the examiner maintains that Grijpma et al. discloses a chewing gum including one or more biodegradable polymers as well as conventional chewing gum ingredients and active agents. The Examiner states that finding the optimum amount of water and flavoring agents to include in the chewing gum would require nothing more than routine experimentation by one reasonably skilled in the art and the use of erythritol is a well known and viable alternative for other sugar alcohol sweeteners disclosed in the primary reference.

(¶7) The Examiner has also rejected claims 40-48 under 35 U.S.C. §103(a) as being unpatentable over Grijpma et al. (USP 5,672,367), in further view of Meyers. In making this rejection, the Examiner argues that it would have been obvious to coat

the chewing gum in Grijpma et al. with a coating as claimed by the Applicant in order to provide storage stability to the chewing gum.

(¶8) The Examiner has also rejected claims 1-30, 32-42, 46, 47 and 49-55 under 35 U.S.C. §103(a) as being unpatentable over Goldberg et al. (WO 01/47368). Goldberg et al. discloses a chewing gum including one or more biodegradable polymers, conventional chewing gum ingredients and coated with a coating syrup. The Examiner states that finding the optimum amount of water and flavoring agents would require nothing more than routine experimentation by one reasonably skilled in the art.

(¶9) Similarly, the Examiner has rejected claim 31 as being unpatentable over Goldberg et al., in view of Grijpma et al., arguing that it would have been obvious to include a medicinal/pharmaceutical ingredient in the chewing gum.

(¶10) The Examiner has also rejected claims 43-45 and 48 under 35 U.S.C. §103(a) as being unpatentable over Goldberg et al. in view of Meyers.

*The Applicants respectfully traverse these rejections.*

Grijpma et al. is directed to biodegradable chewing gum comprising one or more conventional chewing gum components and a gum base having at least one biodegradable polymer selected from the group of polyesters and polycarbonates. Nowhere in Grijpma et al. is the moisture/water content range of the chewing gum addressed. Rather, the moisture/water content in the Grijpma et al. chewing gum is inherent in the chewing gum ingredients – softeners, including glycerin, hydrogenated starch hydrolysate, sorbitol and cane sugar syrup (col. 2, lines 48-52). For instance, hydrogenated starch will typically contain about 25% w/w of water, and sorbitol (fluid form) contains about 15% w/w water. Thus, water is inherently contained in the Grijpma et al. chewing gum, simply through the use of certain standard

ingredients, which already have a *relatively high water content and much higher than the claimed 2% or less level in the pending application.*

Further, there are no teachings in Grijpma et al. regarding an acceptable range for water content in a biodegradable chewing gum. It is well-known to those skilled in the art that high water content in chewing gum comprising biodegradable polymers may cause a degradation problem such that the biodegradable polymers of the chewing gum may be hydrolytically degraded prior to chewing as a result of too much water being present inside the chewing gum. The problem with a low moisture content chewing gum is that it has a less attractive texture and hence additional softeners are needed. The presence of additional softeners (and hence water) in a biodegradable chewing gum makes the biodegradable polymer more vulnerable (paragraph [0008], pending application).

A review of Grijpma et al., Meyers, Li et al. and Goldberg et al. provide no guidance to one skilled in the art as to how much water is needed for a biodegradable chewing gum to have the desired and comparable texture of a non-biodegradable gum and also how to avoid potential premature degradation of the product. Rather, Grijpma et al. only teaches that softeners should account for up to 15% by weight of the chewing gum (col. 2, line 48), even though it is well-known in the art that softeners such as sorbitol, glycerin, and sugar syrup generally contain high percentages of water. Accordingly, one skilled in the art reading Grijpma et al. would conclude that, given the inherent amount of water contained in the ingredients of the chewing gum, that a high water content is necessary in order to achieve a biodegradable chewing gum with the desired texture of a non-biodegradable gum .

Goldberg et al. is directed to improved degradable gum bases comprising condensation copolymers which are polymerized from a first monomer which is

capable of polymerization by condensation polymerization, e.g., ring opening lactone polymerization, and a second monomer which is effective to suppress the crystallization of the copolymer. Goldberg et al. teaches that the copolymers can provide enhanced properties in degradable gum bases made from the copolymers. Goldberg et al. discloses and claims (claim 15) that water uptake is advantageous, wherein the water (moisture) uptake of the copolymer is at least 5% or greater than the water uptake of a homopolymer of the first monomer. Thus, water comprises a substantial portion of the chewing gum described in Goldberg et al. Therefore, a person skilled in the art, reading Goldberg et al., would find no incentive to prepare chewing gum made from biodegradable polymers containing anything less than 5% w/w water as disclosed and claimed in the patent (recall that the claims in the pending application recite a 2% w/w water limit). Additionally, there is no teaching, suggestion or motivation in Goldberg et al. to add any type of medicinally active substance to the low-water content biodegradable chewing gum of the present invention.

Li et al. is directed to “environmentally friendly” chewing gum bases, and resultant chewing gums. The chewing gum base comprises approximately 3 to about 99% by weight poly(lactic acid) copolymers selected from the group consisting of poly(lactic acid-dimer-fatty acid-oxazoline) copolymers and poly(lactic acid-diol-urethane) copolymers. There is no teaching or suggestion in Li et al. regarding the water content necessary in the “environmentally friendly” chewing gum base so that it possesses the same desirable texture and tactile characteristics as non-biodegradable gum bases. Li et al. merely discloses and claims that the chewing gum comprise a water soluble portion and a water insoluble base. Additionally, there is no teaching,

suggestion or motivation in Li et al. to add any type of medicinally active substance to a biodegradable chewing gum having 2% or less water content.

Therefore, the teachings of Grijpma et al., Meyers, Goldberg et al. and Li et al. do not teach, suggest or motivate one skilled the art to have a biodegradable chewing gum can have a water content of less than 2% and still expect that it possess the same desired texture qualities of a traditional, non-biodegradable chewing. In fact, these references teach away from low moisture (water) content chewing gums, because one skilled in the art would know that water content is critical in giving the gum its necessary tactile and texture qualities, which are important to the consumer.

Consequently, in view of the above arguments, the rejections under 35 U.S.C. §103(a), have been overcome and should be withdrawn.

#### **Double Patenting Rejection**

Claims 1-55 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-62 of co-pending US application 10/472,122; claims 1-54 of co-pending US application 10/472,154; claims 1-67 of co-pending US application 10/528,926; claims 1-64 of co-pending US application 10/528,930; claims 1-57 of co-pending US application 10/528,957; claims 1-20, 22-26, and 28-42 of co-pending US application 10/529,133; and claims 1, 2, 10, 11, 13-18, 24-26, and 28-54 of co-pending US application 11/088,109.

Upon indication of allowable subject matter in this case, Applicants will file the appropriate terminal disclaimers in order to overcome these rejections.

The present application as amended herein, is now in form for allowance and early reconsideration and allowance of the claims, as currently pending, is earnestly solicited.

Respectfully submitted,

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I hereby certify that this correspondence is being electronically filed with The Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, this 21st day of May 2008.

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